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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,703	04/26/2001	Hermann Lubbert	STERN 1.001APC	1875
20995	7590	11/02/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			QIAN, CELINE X	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1636	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,703

Applicant(s)

LUBBERT, HERMANN

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,13-15,17,18,20,22-28,30-34,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-7,13,17,18,20,23-28 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,14,15,22,33,34,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1, 3-8, 13-15, 17, 18, 20, 22-28, 30-34, 37 and 38 are pending in the application.

Claims 1, 3-7, 13, 17, 18, 20, 23-28, 30-32 are withdrawn from consideration for being directed to non-elected subject matter. Claims 8, 14, 15, 22, 33, 34, 37 and 38 are currently under examination.

This Office Action is in response to the Amendment filed on 8/26/04.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/26/04 has been entered.

Response to Amendment

The rejection of claim 14 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claim.

The rejection of claims 8, 14, 15, 22, 33, 34, 37 and 38 under 35 U.S.C. 112 1st paragraph (written description) has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 8, 14, 15, 22, 33, 34, 37 and 38 under 35 U.S.C. 112 1st paragraph (enablement) is maintained for reasons set forth of the record mailed on 11/20/03 and further discussed below.

Claim 14 is rejected under 35 U.S.C. 112 2nd paragraph for reasons discussed below.

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Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 14, 15, 22, 33, 34, 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, Applicants provide a declaration showing an example of a transgenic mouse obtained by the claimed method. Applicants assert that this transgenic mouse, having a mutant parkin2 gene with a deletion of the exon 3, exhibits behavioral impairments such as reduced homecage activity, deficit in habituation to a novel environment, abnormality of dopaminergic system, and altered anxiety-related behavior. Applicants thus conclude that the claimed parkin2 mouse is useful in investigating the role of parkin2 gene disruption on various types of animal behavior.

These arguments have been fully considered but deemed unpersuasive. The instant claims are drawn to a transgenic mouse having a polynucleotide encoding a mutant parkin2 protein as listed in Table 1 and 2 in the specification, and a method of producing said transgenic mouse. Based on the teaching of the prior art, the production of transgenic mouse with a specific phenotype is unpredictable because of essential genetic control elements and genetic background varies from species to species (see page 5 of the previous office action mailed on 1/28/03).

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Although the example given in the Declaration demonstrated behavioral abnormality of a parkin2 knockout transgenic mouse, it does not extend the predictability of same phenotype for transgenic mouse with other types of mutation as listed in Table 1 and 2. As such, the claimed transgenic mouse having other types of mutation in the parkin2 gene is not enabled for reasons discussed in the previous office actions mailed on 1/28/03 and 11/20/03.

The Declaration by Dr. Lubbert has been considered thoroughly. However, it does not support the enablement of the claimed invention. For the enablement of the claimed invention, the specification has to teach not only how to make, but also how to use the claimed invention. Although the Declaration provides guidance on how to make a parkin2 knockout mouse, it fails to provide support on how to use said mouse according to the embodiments taught by the instant specification. The specification teaches that the parkin2 mutant mouse can serve as animal model for neurodegenerative diseases, especially Parkinson's disease, and screen for drugs and therapy for the treatment of such diseases. However, the disclosed phenotype of said parkin2 knockout mouse does not appear to resemble any symptoms of any neurodegenerative disease. Since the dopamine neurons appear to be normal in the homozygous parkin2 knockout mouse (see exhibit 3), it certainly cannot serve as an animal model for Parkinson's disease. The statement "the claimed parkin2 mouse is useful in investigating the role of parkin2 gene disruption on various types of animal behavior" is an invitation for further research on the role of parkin2 which Applicants apparently do not know. As such, without teaching from the specification, one skilled in the art would have to engage in undue experimentation to use the claimed invention. Since the claimed mouse is not enabled, the method of making said mouse is also not enabled. Therefore, this rejection is maintained.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 22, 34 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "or rat" in last line. There is insufficient antecedent basis for this limitation in the claim. It is unclear how to get a transgenic mouse by mating with a rat.

In addition, the recitation of "introducing said vector into embryonic stem cells;" renders the claim indefinite because it is unclear which species does the embryonic stem cells belong to. Transgenic mouse can only be generated from mouse embryonic stem cells, not any other embryonic stem cells. Clarification is required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

A handwritten signature in black ink, appearing to read 'Celine Qian', with a stylized, flowing script.